IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re Neurontin® Antitrust Litigation MDL Docket No. 1479 Master Docket No. 02-CV-1390	**VIA ELECTRONIC FILING** Hon. Faith S. Hochberg, U.S.D.J. Hon. Michael A. Hammer, U.S.M.J.
THIS DOCUMENT RELATES TO: ALL OPT-OUT ACTIONS	MDL No. 1479 Master File No. 02-1390 Civil Action Nos. 02-5583 (FSH) 11-2004 (FSH)

DEFENDANTS' RESPONSE BRIEF ON CAUSATION

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PRELIMINARY STATEMENT

At long last, Opt-outs have abandoned one of their two speculative causation scenarios, effectively conceding they cannot raise an issue of fact to sustain it. The Court should therefore enter summary judgment dismissing Scenario 2, and we do not discuss it further below.

Opt-outs focus their efforts on trying to raise an issue of fact as to one of the several links in the chain of causation necessary to sustain Scenario 1. They make no effort to show there is a triable issue with respect to the two earlier, equally critical links in the chain of causation. And their efforts to raise an issue of fact with respect to that single link make clear that it is entirely a lawyer-driven creation without any factual basis. The Court should grant summary judgment dismissing Scenario 1 as well.

Opt-outs fail to confront their burden to show that Pfizer's patent litigations were objectively unreasonable—in other words, that no plaintiff could have believed it might win, and that no plaintiff could have filed them for any basis other than to benefit from automatic regulatory stays. Instead, Opt-outs use out-of-context snippets from Pfizer's documents to focus their attack on the irrelevant issue of its subjective desire to continue to profit from Neurontin. That is no panacea. It is not relevant whether Pfizer had a profit motive—of course it did. Nor is the issue whether it marketed Neurontin off-label. Pfizer pleaded guilty to

doing so and paid a large fine in reparation. The relevant issues are whether Pfizer caused the delay of generic entry by (1) filing or maintaining the '476, '479 ***and*** '482 patent lawsuits because no reasonable plaintiff could have anticipated it might win those litigations or (2) intentional, bad faith delay in securing issuance of the '482 patent.

On these points the record is unequivocal. A reasonable plaintiff could have expected to win the '476 and '479 patent litigations, and Opt-outs appear to have abandoned any argument to the contrary. A reasonable plaintiff could have expected to win the '482 patent litigations as well, and the judge hearing those cases said as much. Such preliminary expressions of opinion by a judge, of course, do not bind the judge, but it is hard to think of a more objective assessment of the likelihood of success.

There is no evidence that Pfizer intentionally delayed issuance of the '482 patent. The entire record is to the contrary. The critical evidence in persuading the Patent Office to issue the patent was not discovered until ***after*** the time Opt-outs say the patent should have been issued. That discovery occurred through a happenstance meeting between an in-house patent lawyer and a German scientist in a Swiss airport in March of 1999. There is no way Opt-outs can move that meeting back in time, and they do not even try. All they offer to support their theory of delay is the testimony of a paid expert who testified that they told him to

assume intentional delay.

ARGUMENT

Opt-outs now look only to Scenario 1 to try to prove causation. Without proof for ***all*** the necessary links, this scenario fails. Opt-outs focus their defense of this theory of causation on just one element—a hypothetical event that would have "triggered" the running of Purepac's exclusivity, which, in turn, would have allowed other generic manufacturers to enter earlier than October 2004. Even if proof of that element alone were enough to sustain Scenario 1 (and, as discussed in Pfizer's opening brief, it is not), the two triggers Opt-outs have concocted are based on pure speculation.[1] In fact, the record on these two trigger events is clear—any reasonable litigant in Pfizer's place would have understood it was winning its case against Apotex, and Pfizer did not have the information needed for issuance of the '482 patent any earlier.

As this Court observed, the prosecution of patents and patent infringement lawsuits generally cannot give rise to antitrust liability because they are *Noerr*-immune. *See In re Neurontin Antitrust Litig.*, Civ. A. No. 02-1830

[1] Opt-outs have abandoned their third Scenario 1 trigger: Pfizer voluntarily dismissing its '482 litigation against Purepac and agreeing to entry of a final order, allowing Purepac to enter the generic market earlier than it did in the actual world. Opt-outs now evidently agree that (1) Purepac's settlement with Pfizer and (2) Purepac's admissions that (a) Pfizer likely would have won the infringement action and (b) it never considered a non-infringing alternative preclude this causation theory.

(FSH), 2009 WL 2751029, at *8 & n.28 (D.N.J. Aug. 28, 2009). Such conduct is actionable only if a plaintiff can establish that it is "sham." Because Opt-outs have no proof Pfizer's conduct was objectively baseless, it is *Noerr*-immune.[2] *See Prof'l Real Estate Investors, Inc.* v. *Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-62 (1993).

A. Opt-outs Cannot Raise an Issue of Fact That Pfizer Should Have Voluntarily Dismissed the '482 Case Against Apotex or Agreed to Entry of Final Judgment

Opt-outs' "primary" trigger for causation involves Apotex winning summary judgment in the '482 case by March 2001 and receiving an unappealable order by April 2001. (Pls. Br. (Dkt. No. 741) at 9-11, 15.) They argue that Pfizer had enough facts that it should have given up its infringement case against Apotex

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[2] The documents Opt-outs cite in their opening brief do not connect the '476 and '479 Orange Book listings to any illegal scheme, nor do they establish that Pfizer filed its '476 and '479 patent infringement cases in bad faith. The 1995 marketing document Opt-outs cite plainly states that in-house counsel's advice related only to the expiration ***of the '544 patent***. (JSUF ¶ 125.) Opt-outs rely on documents from 1997 and 1998 to demonstrate that Pfizer was "desp[e]rate for a way to capitalize on the unanticipated success of Neurontin" and "realized that it could use litigation to delay generic competition." The '476 and '479 patents were submitted in January 1994—when, according to Opt-outs, Pfizer still had modest expectations for Neurontin and years before Pfizer allegedly hatched its plan. (JSUF ¶ 137.) Opt-outs also rely on two Pfizer marketing documents from late 2000 (well after the suits were filed) as purported evidence that Pfizer believed its infringement claims lacked merit. Neither addresses Pfizer's prospects for success in its litigations. One simply notes that ANDAs could be approved once the Hatch-Waxman stays resulting from the suits expired. (JSUF ¶ 134.) The other states that the '476 and '479 patents "are not expected to provide any additional protection against generics," but only in the context of a discussion of the '482 patent and its 2017 expiration date. (JSUF ¶ 136.)

when Apotex moved for summary judgment. But as shown in Pfizer's opening brief (Dkt. No. 742 at 7-10), at the time Apotex moved for summary judgment, Pfizer had a reasonable basis to believe its claim construction was correct, that Apotex infringed the patent and that its lawsuit could be successful.

In its motion for summary judgment, Apotex argued that its generic product was non-infringing because it included adjuvants that "should be avoided" according to the '482 patent. (*See* DSUF (Dkt. No. 619)[3] ¶ 29.) Apotex's motion thus turned on whether the '482 patent excluded the use of these adjuvants, or (as Pfizer argued) instructed that adjuvants be selected carefully to create stable gabapentin formulations. *See In re Gabapentin Patent Litig.*, MDL No. 1384, 2005 WL 4066434, at *6 (D.N.J. Aug. 22, 2005). In addressing the same issue during a hearing on an injunction application, Judge Lifland stated: "I am ***inclined*** at this point ***to agree with [Pfizer] on its claim construction both as to adjuvants*** and as to the chloride aspect of the '482 patent." *In re Gabapentin Patent Litig.*, MDL No. 1384, Trial Tr. at 13 (D.N.J. Oct. 13, 2004) (7/2/12 Francis Decl., Ex. 33) (emphases added); (DSUF ¶¶ 31-33). If the federal judge hearing the '482 cases believed that Pfizer was winning this issue, a reasonable jury would have to

[3] Pfizer's opening brief inadvertently referenced another version of Defendants' Statement of Undisputed Facts, Dkt. No. 591. The paragraph citations to the DSUF in the opening brief in fact correspond to Dkt. No. 619.

conclude that a reasonable, objective litigant could have the same view.[4]

In an attempt to buttress their argument on the ***timing*** of an Apotex victory, Opt-outs point to the opinion of a Pfizer expert in the patent cases on the ***effect*** of an Apotex victory. (Pls. Br. at 10-11.) The Court should not be fooled by such sleight of hand. Pfizer agrees with Opt-outs that a final court decision in favor of Apotex on the '482 patent would have triggered Purepac's exclusivity and permitted Apotex to enter the market 180 days later.[5] But Pfizer disagrees that it should have acquiesced to such a judgment before Judge Lifland decided the issue. There simply is no evidence to show that Apotex would or could have won summary judgment—much less an unappealable final order—by April 2001.[6]

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[4] The gap between the time Apotex moved for summary judgment and the time Judge Lifland decided that motion was due in part to the '482 actions against Purepac, Apotex, Teva, Eon, and Zenith/Ivax being filed at various times and later consolidated in this Court, and to the Court's deciding at one time all ten motions for summary judgment (either for infringement or for non-validity) that those generics filed against Pfizer. (*See* JSUF ¶¶ 222, 230.) The issues of claim construction were novel and complex, providing more proof that Pfizer behaved as a reasonable litigant in contesting summary judgment.

[5] A final court decision has been interpreted to mean a final order or judgment from a court from which no appeal can be or has been taken. (JSUF ¶ 236.)

[6] Opt-outs suggest Pfizer's desire "to preserve its monopoly in the marketplace for as long as possible" and avoid triggering Purepac's exclusivity in the '476 litigation was somehow inappropriate. But that did not trouble the district court presiding over that litigation, as it later denied the defense motion seeking attorneys' fees. (JSUF ¶¶ 176, 178.) And for good reason. All companies seek to maintain their pricing advantage for as long as possible. The only relevant issue for the Court is whether those efforts were legally permissible or were antitrust misconduct.

B. Opt-outs Cannot Raise an Issue of Fact That the '482 Patent Could Have Issued by August 1998, That Apotex Would Have Had a Final Judgment by October 2001 or That Pfizer Would Not Have Appealed

Opt-outs' "alternative" trigger involves earlier issuance of the '482 patent (by August 1998), leading to a final decision for Apotex by October 2001, clearing the way for Apotex and other generics to enter once Pfizer's regulatory exclusivity expired in December 2002. (Pls. Br. at 11-15.) The unrebutted deposition testimony of Dr. Frank Tinney establishes that Pfizer did not obtain the information needed to convince the U.S. Patent and Trademark Office to issue the patent until March 1999, and it took a year thereafter to convince the Patent Office to issue the patent. (JSUF ¶ 86.)

Opt-outs make no effort to refute this. Instead, they rely entirely on their proffered patent expert, Robert Carl Moy, to say that the patent could have issued by August 1998 if Pfizer had not asked for numerous extensions during its prosecution, and then they simply argue that a court decision of non-infringement in favor of Apotex would have come at least six months before December 2002. Again, as set out in Pfizer's opening brief (at 10-11), Opt-outs' position that the '482 patent could have issued earlier than it actually did is without support in the record, and their position that Pfizer should have conceded in 2001 a case that the presiding judge believed it was still winning more than three years later is without basis.

Moreover, there is no evidence connecting the '482 patent prosecution to an alleged overall scheme to block generic entry. Opt-outs cannot cite any document or testimony to establish such a connection, nor does Professor Moy purport to offer such a link.[7] (*See* DSUF ¶¶ 21-25; 7/2/12 Francis Decl., Ex. 9 ("Moy Tr.") at 40 ("[T]o the extent that you are asking me, do I have an understanding of how [the '482 prosecution] fits into the large picture, yeah, no, I don't understand what the large picture is.").) He merely opines that Pfizer's pattern of seeking extensions during the patent prosecution is suspicious (DSUF ¶¶ 21-23; Moy Tr. at 94, 152, 199, 251) based on his understanding from Opt-outs' counsel that the "delay" allowed Pfizer "to get a more efficient sequential spacing . . . of the various stay periods." (DSUF ¶ 22; Moy Tr. at 94-95, 232-33, 236; 7/2/12 Francis Decl., Ex. 10 ("Moy Rep.") ¶ 80.)

Put simply, Professor Moy's suspicion simply does not constitute evidence sufficient to get past summary judgment. *See Reazin* v. *Blue Cross & Blue Shield of Kan., Inc.*, 663 F. Supp. 1360, 1479 (D. Kan. 1987) ("Theoretical speculation, unsupported assumptions and conclusory allegations advanced by an expert are neither admissible at trial, nor are they entitled to any weight when

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[7] Because Opt-outs have no evidence that this patent prosecution was part of the alleged scheme, it is *Noerr*-immune, and any harm flowing from it cannot constitute antitrust injury. *See Brunswick Corp.* v. *Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (antitrust injury cannot flow from conduct that is not prohibited under the antitrust laws).

raised in opposition to a motion for summary judgment." (citations omitted)), *aff'd*, 899 F.2d 951 (10th Cir. 1990); *Kramer* v. *Exxon Mobil Corp.*, Civ. A. No. 07-0436 (FSH), 2009 WL 1544690, at *5 (D.N.J. June 3, 2009) (plaintiffs' "suspicion" that defendant engaged in discriminatory conduct not sufficient to withstand summary judgment).

CONCLUSION

Opt-outs attempt to defend just one element of one theory of causation. Even if that element were enough to sustain the theory, the record is clear on the two hypothetical trigger events on which Opt-outs rely to satisfy that element. Opt-outs have not raised—and cannot raise—a genuine issue of material fact as to that, or any other, aspect of causation. For the foregoing reasons, and for the reasons set out in its opening brief, Pfizer respectfully submits that summary judgment in its favor is appropriate.

Dated: June 27, 2014

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